Listing of the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

1 - 76. (Cancelled)

77. (New) A method for preparing a sterile pharmaceutical composition of a steroid comprising:

(i) dissolving a non-sterile steroid in a solvent to yield a solution of the steroid,

(ii) filtering the solution to yield a sterile solution,

(iii) combining the sterile solution with sterile water to form a suspension,

(iv) optionally removing all or part of the solvent,

(v) treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm,

(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a suspension of the steroid having a mass median diameter less than 10μm, and

(vii) storing the sterile pharmaceutical composition in sterile containers.

78. (New) The method of claim 77, wherein the non-sterile steroid is a powder.

79. (New) The method of claim 78, wherein the powder is a micronized powder.

80. (New) The method of claim 77, wherein the steroid is budesonide.

81. (New) The method of claim 77, wherein the steroid is fluticasone.

82. (New) The method of claim 77, wherein the solvent comprises an alcohol.

83. (New) The method of claim 77, wherein the solvent comprises a Class 3 solvent.

84. (New) The method of claim 77, wherein the solvent comprises a Class 2 solvent.

85. (New) The method of claim 77, comprising combining solvent with the steroid at a temperature from 20°C below the boiling point of the solvent up to its boiling point.

86. (New) The method of claim 85, wherein the solvent is at reflux.

87. (New) The method of claim 77, comprising removing solvent under reduced pressure.

88. (New) The method of claim 77, comprising removing solvent at atmospheric pressure.

89. (New) The method of claim 77, comprising filtering the solution through a filter having a pore size of 0.2μm or less.

90. (New) The method of claim 77, wherein the sterile water contains a surfactant.

91. (New) The method of claim 77, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

92. (New) The method of claim 91, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

93. (New) The method of claim 77, comprising storing the sterile composition in sterile ampoules.

94. (New) A method for preparing a sterile suspension of budesonide, comprising:
(i) dissolving non-sterile budesonide in a solvent to yield a budesonide solution,
(ii) filtering the solution to yield a sterile solution,
(iii) combining the sterile solution with sterile water to form a suspension of budesonide,
(iv) optionally removing all or part of the solvent,
(v) treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm,
(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising the suspension of budesonide having a mass median diameter less than 10μm, and
(vii) storing the sterile pharmaceutical composition in sterile containers.

95. (New) The method of claim 94, wherein the solvent comprises an alcohol.

96. (New) The method of claim 94, comprising filtering the solution through a filter having a pore size of 0.2μm or less.

97. (New) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

98. (New) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

99. (New) A method for preparing a sterile suspension of fluticasone, comprising:-

(i) dissolving non-sterile fluticasone in a solvent to yield a fluticasone solution,

(ii) filtering the solution to yield a sterile solution,

(iii) combining the sterile solution with sterile water to form a suspension of fluticasone,

(iv) optionally removing all or part of the solvent,

(v) treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm,

(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising the suspension of fluticasone having a mass median diameter less than 10μm, and

(vii) storing the sterile pharmaceutical composition in sterile containers.

100. (New) The method of claim 99, wherein the solvent comprises an alcohol.

101. (New) The method of claim 99, comprising filtering the solution through a filter having a pore size of 0.2μm or less.

102. (New) The method of claim 101, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

103. (New) The method of claim 101, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

104. (New) A sterile suspension of a steroid, obtained by the method of claim 77.

105. (New) A sterile suspension of budesonide, obtained by the method of claim 97.

106. (New) A sterile suspension of fluticasone, obtained by the method of claim 102.